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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>6</sup>:</b> <b>A61N 1/39, 1/362</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 99/03534</b> <b>(43) International Publication Date:</b> 28 January 1999 (28.01.99)
<b>(21) International Application Number:</b> PCT/US98/14751 <b>(22) International Filing Date:</b> 17 July 1998 (17.07.98)  <b>(30) Priority Data:</b> 60/052,881      17 July 1997 (17.07.97)      US 60/052,891      17 July 1997 (17.07.97)      US 60/079,514      26 March 1998 (26.03.98)      US  <b>(71) Applicant (for all designated States except US):</b> CPR MEDICAL, INC. [US/US]; 2425 Ridgecrest Drive Southeast, Albuquerque, NM 87108 (US).  <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> SCHULER, Eleanor, L. [US/US]; 2201 Spruce Needle Road, Rio Rancho, NM 87124 (US). SCOTT, Dale, L. [US/US]; 4221 Purple Sage Northwest, Albuquerque, NM 87120 (US).  <b>(74) Agent:</b> MYERS, Jeffrey, D.; Peacock, Myers & Adams, P.O. Box 26927, Albuquerque, NM 87125-6927 (US).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i> <i>With amended claims and statement.</i>
<b>(54) Title:</b> DEFIBRILLATOR/PACEMAKER  <b>(57) Abstract</b> <p>A monolithic device (10) for providing defibrillation and pacing of a heart by engaging pacing circuitry once defibrillation has been accomplished. Defibrillation and pacing of a human heart from outside the body employs defibrillation circuitry having an electromotive force of less than or equal to approximately 200 volts. Digital circuitry for generating a direct current waveform to the heart is employed.</p> <div style="text-align: right;"> </div>		

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## DEFIBRILLATOR/PACEMAKER

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CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of the filing of U.S. Provisional Patent Application Serial No. 60/052,881, entitled *System for Control of Cardiac Arrhythmia*, filed on July 17, 1997; U.S. Provisional Patent Application Serial No. 60/052,891, entitled *Method to Stop Fibrillating Human or Animal Heart*, filed on July 17, 1997; and U.S. Provisional Patent Application Serial No. 60/079,514, 10 entitled *Electronic Waveform and Generating Devices for Treating Cardiac Arrhythmia*, filed on March 26, 1998; and the specifications thereof are incorporated herein by reference.

BACKGROUND OF THE INVENTIONField of the Invention (Technical Field):

15 The present invention relates to methods and apparatuses for controlling cardiac muscles, in particular for correcting arrhythmias.

Background Art:

Existing devices for treating cardiac arrhythmia require deployment of high voltages which can, 20 and often do, cause injury to the patient. The present invention permits utilization of low voltages and greatly decrease the risk of further injury to the patient.

An arrhythmia is any abnormal electrical contraction of heart. Particular arrhythmias include: asystole -- no beat at all or "flat-line" on monitor; bradycardia -- slow beat, less than 60 beats per 25 minute; tachycardia -- fast beat, over 100 beats per minute; and fibrillation -- life threatening chaotic heart action in which the heart twitches or quivers rapidly and is unable to pump efficiently.

During fibrillation, less blood is circulating and thus all systems of the human or animal body are at risk. The longer fibrillation continues unchecked the more likely death will occur. For every 30 minute of fibrillation, a 10% reduction of life potential is subtracted, i.e., ten minutes results almost

certain death. During fibrillation the electrical system of the heart is disorganized and erratic. The normal rhythmic beat is totally lost. Serious life threatening events begin to occur. Breathing becomes erratic and then stops as electrical failure begins. Shortly the inadequate circulation of blood causes organs and tissues to be oxygen starved and cell death begins. When brain and heart muscle oxygen starvation reach crisis points they begin to die and hence the entire body begins to die. At some point the heart fibrillations are not reversible and death of the human or animal occurs. It is important to stop fibrillation and to restart or regain the same level of heart contractions to oxygenate the entire body properly.

Fibrillation is currently typically treated by an electronic defibrillator which delivers a shock via two hand-held paddles. This process is familiar to those who view medical television shows and witness a shock so great that the entire body jumps. This shock is about 2,000 to 5,600 volts for external shocks and 310 to 750 volts for internal defibrillators. Repeated use of such large electrical shocks likely may damage the nervous system to such an extent that disabilities shall be present even if the patient lives. The popular conception is that a defibrillator "puts" a heart beat into a stopped heart. Actually, a defibrillator stops the quivering heart, after which, but not always, the heart may resume a slow beat (bradycardia). Paramedics then can use medications to speed up the heart and/or administer an emergency external pacemaker while transporting the victim to a hospital.

In the science of electromyography there is a graphical presentation of fibrillation on a visual monitor of a heart muscle being affected by a monophasic, biphasic or triphasic spike usually of 25 to 100 microvolts in amplitude and each less than 2 milliseconds in duration. These represent uncoordinated contractions of heart muscle (myocardium) fibers. This is a degrading and dangerous state and does require electrical intervention plus oxygen and cardiac medications in an effort to stabilize or regain a normal heart beat. Perhaps 40% of heart attack victims are in fibrillation when a paramedic arrives. Another 40% might be in bradycardia, tachycardia or asystolic status. The other 20% might have plugged heart blood vessels, bleeding, or other conditions that are not related to the electrical function of the heart muscle.

The present invention provides devices and methods whereby substantially lower voltages and currents may be used to successfully treat heart muscle arrhythmias.

SUMMARY OF THE INVENTION (DISCLOSURE OF THE INVENTION)

5       The present invention is of a monolithic device for providing defibrillation and pacing of a heart comprising: defibrillating circuitry and pacing circuitry which engages once defibrillation has been accomplished. The invention is also of a device for providing defibrillation of a human heart from outside the body comprising defibrillation circuitry having an electromotive force of less than or equal to approximately 200 volts. The invention is further of a device for providing pacing of a human  
10 heart from outside the body comprising pacing circuitry having an electromotive force of less than or equal to approximately 200 volts. The invention is additionally of a device for providing defibrillation of a heart comprising digital circuitry for generating a direct current waveform to the heart. The invention is yet further of a device for providing pacing of a heart comprising digital circuitry for generating a direct current waveform to the heart.

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The invention is also of a method for providing defibrillation and pacing of a heart comprising: defibrillating the heart; and pacing the heart within approximately 20 msec of cessation of step a). The invention is further of a method for providing defibrillation of a human heart from outside the body comprising defibrillating with an electromotive force of less than or equal to approximately 200  
20 volts. The invention is additionally of a method for providing pacing of a human heart from outside the body comprising pacing with an electromotive force of less than or equal to approximately 200 volts. The invention is still further of a method for providing defibrillation of a heart comprising digitally generating a direct current waveform to the heart. The invention is yet further of a method for providing pacing of a heart comprising digitally generating a direct current waveform to the heart.

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A primary object of the present invention is to provide means by which substantially lower voltages and currents can be used to control cardiac arrhythmias.

A primary advantage of the present invention is that it is lightweight yet can operate for  
30 durations of three hours or more.

Other objects, advantages and novel features, and further scope of applicability of the present invention will be set forth in part in the detailed description to follow, taken in conjunction with the accompanying drawings, and in part will become apparent to those skilled in the art upon  
5 examination of the following, or may be learned by practice of the invention. The objects and advantages of the invention may be realized and attained by means of the instrumentalities and combinations particularly pointed out in the appended claims.

#### BRIEF DESCRIPTION OF THE DRAWINGS

10 The accompanying drawings, which are incorporated into and form a part of the specification, illustrate several embodiments of the present invention and, together with the description, serve to explain the principles of the invention. The drawings are only for the purpose of illustrating a preferred embodiment of the invention and are not to be construed as limiting the invention. In the drawings:

15 Fig. 1 is a perspective view of the preferred control unit of the invention;

Fig. 2 is a graph of the counter-fibrillation (C-FIB) waveform of the invention followed by immediate external pacing, with body resistance of 50 ohms, C-FIB energy of 400 joules, pacing rate  
20 and pulse width of 60 bpm and 20 msec, and pacing current of 200 mA 5 seconds after C-FIB;

Fig. 3 follows Fig. 2, but with a body resistance of 100 ohms;

Fig. 4 follows Fig. 2, but with a body resistance of 200 ohms;

25 Fig. 5 follows Fig. 2, but with a C-FIB energy of 144 joules;

Fig. 6 is a schematic of the preferred hardware of the invention;

30 Fig. 7 is a diagram of the preferred switch settings of the hardware of Fig. 6;



Figs. 8(a)-(c) is an electrical schematic of the preferred waveform generation circuitry of the invention;

5 Fig. 9 describes the pins shown in Figs. 8(a)-(c);

Figs. 10(a)-(b) is a schematic of the board components corresponding to Fig. 6;

Figs. 11(a)-(b) is a trace diagram of the solder side of the board corresponding to Fig. 6;

10 Figs. 12(a)-(b) is a trace diagram of the component side of the board corresponding to Fig. 6;

and

Figs. 13(a)-(b) is a schematic of the board component slots corresponding to Fig. 6.

15 DESCRIPTION OF THE PREFERRED EMBODIMENTS

(BEST MODES FOR CARRYING OUT THE INVENTION)

The present invention is of a system to control human and animal hearts to treat arrhythmias. The invention is intended to override an impaired human or animal heart electrical system and to provide a life-sustaining heart beat. In an external embodiment, the invention superimposes and conducts electrical current via stick-on, non-invasive electrode pads to stop damaging or inefficient heart contractions or fibrillation. In addition electrical energy is applied to the heart in a manner that captures its control and serves as the regulatory force to compel the heart to contract in a manner that circulates blood throughout the body. The purpose of the system is to cause all four chamber of the heart to contract forcefully so as to pump blood and immediately relax so as to allow all four cardiac chambers to fill with blood. The capture of the heart is aimed and causing a pumping and refilling of blood at a rate that causes oxygenation of humans or animals tissues and organs in a manner consistent with life. While the device contracts all four chambers of the heart simultaneously, the normal heartbeat contracts the upper (atrial) chambers first and then the lower (ventricular) chambers last.

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Referring to Fig. 1, the device 10 of the present invention provides for the electrical control of the heart muscle and preferably presents electronically monitored feedback on a small screen 12 to provide understandable data for medical personnel. The screen allows presentation of the sinus wave shape, heart rate and records and stores this information for medical record usage. Preferably, voice messages prompt the paramedic after the pacing and sensing electrodes have been applied to the patient, including: (1) no detectable beat - check connections; (2) fibrillation or erratic beat; (3) bradycardia; (4) tachycardia; and (5) stable heartbeat. The main use of the external embodiment of the invention is for first-responder treatment of acute cardiac emergencies, being non-invasive in that it does not pierce the skin.

The use of the present invention for the resuscitation of animals ranging in size from small dogs up to large zoo-kept mammalian species is possible with lower or higher power units for correspondingly smaller or larger hearts than humans have. The heart resuscitation animal models indicate that the larger the animal the larger the heart and the more power will be required to control that heart. The human electronic device is appropriate to treat both adults and children. To accomplish this, the device preferably features an operator controlled amplitude range of sufficient expanse to cover anticipated patient size and hydration status.

The invention is preferably sealed to be usable in wet environments and may be cleaned and disinfected with selected chemical disinfectants. The external embodiment is powered by, for example, one or more rechargeable 12-volt lead-acid gel batteries within the main section 14. In addition, a cylindrical handle 16 located on the left side of the unit houses alkaline D-cells. The D-Cells can be changed while pacing or counter-fibrillation continues via the internal 12-volt battery(ies).

The invention preferably combines counter-fibrillation with assessment and control functions. Counter-fibrillation utilizes relatively low (less than approximately 200 volts) electrical energy which calms or contracts the heart for 1/2 to 5 seconds and then runs a pacing program (preferably five

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to 60 seconds, and most preferably 25 seconds) followed by operator selection of subsequent pacing rates and modes. There are two pacing modes, demand or fixed.

In the external embodiment, up to a certain number (preferably four, three or up to six being acceptable) of sensing pads (approximately 1.5 inches diameter) are placed on the chest and/or back or on pulse points found at the wrists or elsewhere on the body to detect rate of heart function. The sensing pads lead to electronics that immediately report cardiac performance or lack of it. That information is flashed on a screen for operator interpretation. Such information includes basal heartbeat rate, if any, and determines if it is chaotic fibrillation, no-beat or too slow or fast. In addition, it is determined if the heart is fibrillating or is asystolic.

Figs. 6-13 illustrate the preferred hardware of the invention, including a programmable logic controller, an external transcutaneous pacemaker, an interface circuit board, and a battery pack. The programmable logic controller preferably includes customizable software, 24 inputs, 32 outputs, two kilobytes of reprogrammable memory, and input/output expansion capabilities. The external transcutaneous pacemaker provides a constant current source up to 300 ohms, discrete amplitude range adjustment from 20-200 mA in 10 steps, discrete rate range adjustment from 40-220 bpm in 10 steps, fixed and demand mode pacing, adjustable pacing duration from 20-100 msec, and complete manual and software control.

The interface circuit card provides a counter-fibrillation voltage of 3-192 volts, programmable logic input definition switches, programmable logic outputs, and DC power utilization. Example inputs and outputs are shown in Figs. 6-7. Input switches may include counter-fibrillation duration of .5-5 sec over 10 steps, pacer current amplitude starting point from 20-200 mA, counter-fibrillation amplitude setting least significant nibble, pacer rate starting point from 40-220 bpm, counter-fibrillation battery level most significant nibble with two upper bits set as "Don't Care" for use as a 2<sup>n</sup> multiplier which extends the maximum voltage from 48 to 192 volts, pacer pulse duration of 0-512 msec with 32 msec resolution, choice of routines, and start/stop control. Output switches may include 3-192 volts over 20 outputs, master output control, counter-fibrillation and pacing output

control selector, biphasic control, pacer on/off, rate, current amplitude, demand/fixed pacing mode, and rate counter reset and pulse duration controls.

5 A number (preferably three) of pacing pads of 8 to 12 square inch electrode area each are placed, such as with two on the chest and one on the back. The impedance of the body is ascertained to select the starting energy levels for both the counter-fibrillation and pacing modes. These pads do multiple duty as they determine impedance and also are used to apply the counter-fibrillation current and/or the appropriate electrical pacing energy.

10 The system detects the heart status any time during the use of the device provided the sensing and counter-fibrillation/pacing pads are in place on the body of the patient. In some instances the small sensing pads provide information and in other cases counter-fibrillation or pacing must stop momentarily (1 to 5 seconds) for information on heart performance to be ascertained.

15 The counter-fibrillation system can apply monophasic, biphasic or triphasic direct current via the pacing pads so as to paralyze the heart muscle (myocardia), but a multiphasic counter-fibrillation waveform is preferred such as discussed in U.S. Provisional Patent Application Serial No. 60/079,514. The time required for stopping fibrillation of the heart shall preferably ranges from 1/2 second up to 5 seconds. Once the heart is counter-fibrillated, the sensors detect calmness or  
20 chaos characteristics of the heart and pacing is initiated at the same instant (preferably within 20 msec) that the counter-fibrillator releases its hold on the myocardia. Pacing is preferably operator controllable from 50 to 200 beats per minute. Initial pacing is automatically applied as part of the counter-fibrillation module. The first beats are at higher electrical amplitude to insure capture and control of the heart. Sensors inform the operator, along with observation of life signs, if capture is  
25 lost. The operator can repeat the pacing program or can raise the amplitude manually to attempt a re-capture and gain electrical control of the heart's biological electrical pacing system.

When pacing is occurring at the rhythm selected by the operator, the operator may elect to engage a demand mode and transport the victim to the hospital. The demand mode "listens" via the  
30 sensors and warns the operator by audible alarm and visually on the monitor screen if capture is lost.

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The operator may try to re-capture by manual control of pacing rate and amplitude or he can default to the pre-programmed pacing event if capture and control of the heart cannot be attained.

The invention, which is battery operated for up to approximately 3 hours, stabilizes a heart  
5 within approximately one minute after applying of the electrodes, provided the operator has arrived  
within about five minutes of a heart attack. The fully charged batteries shall be operative for a  
minimum of 3 hours, but this can be extended by changing the alkaline batteries. Batteries can be  
changed quickly with little or no interruption of pacing once the patient is stable. The cylindrical case  
contains alkaline batteries which can be changed as in a flashlight. The rechargeable internal lead-  
10 acid-gel 12-volt battery(ies) in the main body of the invention supplies electricity while the alkaline  
batteries are changed. The cylindrical battery case also serves as a carry-handle. The 12-volt main  
battery(ies) can also be changed quickly if required. The entire system, including both pacing and  
counter-defibrillation module, preferably weighs less than five pounds. In models without counter-  
defibrillation, the weight preferably is less than three pounds. Weight does not include electrodes,  
15 sensing pads, or the wiring harness.

The present invention is also of a method of gaining emergency electrical control of a  
fibrillating heart. The usual cardiac medications, oxygen administration and other treatment can be  
utilized simultaneously or after cardiac counter-fibrillation treatment is applied. The invention can be  
20 used alone for stopping fibrillation or it can be part of a system that deals with all heart arrhythmias.  
Rather than an analog signal, a digital, software driven, signal of constant direct current is employed  
to bring a fibrillating heart to a stand-still very quickly. This is important because the longer the  
duration, the lower the voltage amplitude. The longer duration and lower voltage amplitude can result  
in the same amount of energy being applied as used today with defibrillators, but usually is much  
25 lower in energy. However, the invention begins at a lower electrical energy and then steps up as  
required until the heart fibrillation ceases. The nominal amount of time applied to each counter-  
fibrillation power level is about 1/2 to 5 seconds.

When the fibrillation has stopped, the counter-fibrillation electrical energy is released by the  
30 software which then instantly activates a special brief burst pacing program to establish a heart beat.

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The burst pacing program can last up to preferably 25 seconds. The energy for this particular heart pacing starts high and with each contraction of the heart steps the electrical energy downward by about 15%. If "capture" of the heart is lost, then sensors increase the next electrical energy pulse by an amount, preferably by 30%. If capture is not regained, the algorithm program returns electrical pulse to the highest pacing power and runs that program as long as capture is maintained while reducing pulse power by 8 to 10% every two or three pulses until it maintains control of the heartbeat at a fixed rate wherein the information aspect of the unit prompts the paramedic to select a fixed rate pacing and adjust the power as he deems appropriate while transporting the patient to a hospital. Capture is determined by sensors that detect either electrical activity via electrode pads, mechanical activity through blood pressure and blood flow detection, or both. The sensors, which may be standard, off-the-shelf items, are fed back to the logic control circuitry that makes decisions based upon the sensor's output.

The paramedic can further tailor the pacing program treatment aspect by continuing fixed-rate pacing or switch over to demand mode which monitors the heart and only paces if the victim's heart beat drops below a selected rate. The paramedic may also select a waveform or waveform variation stored in software of the control system. Thus, if a patient's heart is beating on its own the unit merely stands by to catch any decaying beat rate. Enough beats are inserted during a minute period to equal the amount called for by the paramedic. Rate selection for demand-mode is operable only between 50 and 120 beats per minute. While fixed-rate pacing can be utilized to pace a heart throughout a range of 50 to 200 beats per minute.

The formula for energy utilized for counter-fibrillation is given by  $J = \text{Voltage}^2 \times \text{seconds/Resistance}$ . If the analog signal is transformed into a constant DC signal of greater duration, then a substantial reduction in voltage can be achieved. For example, assume a patient's body resistance is 50 ohms and in order to reset the heart it'll require 360 joules. With the present day analog signal technique, it would take approximately 650 - 1420 volts. Now assume that the new constant DC signal duration is stretched out to .5 seconds. The voltage required to do the same amount of work is now 190 volts. The total voltage can be less than 200 volts but more than 60 volts for adults. Children in fibrillation can be expected to be treated with 40 to 120 volts. The selection of

voltage will be relative to the hydration of the patient and their relative body size and frailty Obviously, a much safer situation for doctors, nurses, emergency personnel and the patient. Implantable device voltages are approximately four to eight times less than voltages needed with non-invasive stick-on electrode pads of the invention.

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The counter-fibrillation signal can be described by a sharp rise in voltage (slope) for approximately 3 to 5 milliseconds, where it will reach the full DC value and then be maintained (held at constant value) for a variable long duration followed by a decay in voltage very similar to the slope of the rise. The method for up slope or down slope may be in small digital steps or angular cascade in many electrical patterns. This electrical signal can also be reversible as to polarity by the operator. The counter-fibrillation force on the heart can be applied from 1/2 second up to 5 seconds. Time and voltage are gradually increased via instructions from the installed program.

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The counter-fibrillation system of the invention and its electrical and electronic controls can be combined with or inserted or added into other emergency cardiac systems as a drop in module. Additionally, the system can be designed into more complex cardiac care systems. It can also be utilized as a stand-alone compact system for first responders to cardiac emergencies.

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The electrical patterns preferred are shown in Figs. 2-5. These electrical patterns indicate some of the approaches to stop fibrillation in a human or animal heart. Some variations of these patterns may be made but the inventors are certain that those presented herewith shall stop fibrillation in both human and animal hearts at much lower power than traditionally used. This invention shall more surely stop fibrillation and directly cause heart pacing to occur and do this faster than is currently possible with pre hospital cardiac victims.

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The present invention may be used to stimulate contractions of other muscles than the heart where desirable.

Although the invention has been described in detail with particular reference to these preferred embodiments, other embodiments can achieve the same results. Variations and

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modifications of the present invention will be obvious to those skilled in the art and it is intended to cover in the appended claims all such modifications and equivalents. The entire disclosures of all references, applications, patents, and publications cited above are hereby incorporated by reference.



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CLAIMS

What is claimed is:

- 5           1.       A monolithic device for providing defibrillation and pacing of a heart, said device comprising:
- means for defibrillating the heart; and
- means for pacing the heart once defibrillation has been accomplished.
- 10           2.       A device for providing defibrillation of a human heart from outside of a human body containing the heart, said device comprising defibrillation means having an electromotive force of less than or equal to approximately 200 volts.
3.       A device for providing pacing of a human heart from outside of a human body
- 15       containing the heart, said device comprising pacing means having an electromotive force of less than or equal to approximately 200 volts.
4.       A device for providing defibrillation of a heart, said device comprising digital means for generating a direct current waveform to the heart.
- 20           5.       A device for providing pacing of a heart, said device comprising digital means for generating a direct current waveform to the heart.

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6. A method for providing defibrillation and pacing of a heart, the method comprising the steps of:

- a) defibrillating the heart; and
- b) pacing the heart within approximately 20 msec of cessation of

5 step a).

7. A method for providing defibrillation of a human heart from outside of a human body containing the heart, the method comprising defibrillating with an electromotive force of less than or equal to approximately 200 volts.

10

8. A method for providing pacing of a human heart from outside of a human body containing the heart, the method comprising pacing with an electromotive force of less than or equal to approximately 200 volts.

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9. A method for providing defibrillation of a heart, the method comprising digitally generating a direct current waveform to the heart.

10. A method for providing pacing of a heart, the method comprising digitally generating a direct current waveform to the heart.

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**AMENDED CLAIMS**

[received by the International Bureau on 07 December 1998 (07.12.98);  
original claims 1,3,6 and 8 amended; remaining claims unchanged (2 pages)]

1. A monolithic device for providing defibrillation and pacing of a heart, said device comprising:  
  
low voltage means for defibrillating the heart; and  
  
means for pacing the heart once defibrillation has been accomplished.
2. A device for providing defibrillation of a human heart from outside of a human body containing the heart, said device comprising defibrillation means having an electromotive force of less than or equal to approximately 200 volts.
3. A device for providing pacing of a human heart from outside of a human body containing the heart, said device comprising pacing means having an adjustable current amplitude range of between approximately 20 milliamps and approximately 200 milliamps.
4. A device for providing defibrillation of a heart, said device comprising digital means for generating a direct current waveform to the heart.
5. A device for providing pacing of a heart, said device comprising digital means for generating a direct current waveform to the heart.
6. A method for providing defibrillation and pacing of a heart, the method comprising the steps of:
  - a) defibrillating the heart with a low voltage; and
  - b) pacing the heart within approximately 20 msec of cessation of step a)with an adjustable current.
7. A method for providing defibrillation of a human heart from outside of a human body containing the heart, the method comprising defibrillating with an electromotive force of less than or equal to approximately 200 volts.

8. A method for providing pacing of a human heart from outside of a human body containing the heart, the method comprising pacing with an adjustable current having an amplitude range of between approximately 20 milliamps and approximately 200 milliamps.

9. A method for providing defibrillation of a heart, the method comprising digitally generating a direct current waveform to the heart.

10. A method for providing pacing of a heart, the method comprising digitally generating a direct current waveform to the heart.

**STATEMENT UNDER ARTICLE 19**

Dear Sir:

In response to the Examiner's comments in the International Search Report mailed on 08 October 1998, Applicants respectfully request amendment of the claims without prejudice as follows:

In the Claims:

1. (Amended) A monolithic device for providing defibrillation and pacing of a heart, said device comprising:  
  
    low voltage means for defibrillating the heart; and  
  
    means for pacing the heart once defibrillation has been accomplished.
2. A device for providing defibrillation of a human heart from outside of a human body containing the heart, said device comprising defibrillation means having an electromotive force of less than or equal to approximately 200 volts.
3. (Amended) A device for providing pacing of a human heart from outside of a human body containing the heart, said device comprising pacing means having an [electromotive force of less than or equal to] adjustable current amplitude range of between approximately 20 milliamps and approximately 200 [volts] milliamps.
4. A device for providing defibrillation of a heart, said device comprising digital means for generating a direct current waveform to the heart.
5. A device for providing pacing of a heart, said device comprising digital means for generating a direct current waveform to the heart.
6. (Amended) A method for providing defibrillation and pacing of a heart, the method comprising the steps of:
  - a) defibrillating the heart with a low voltage; and
  - b) pacing th heart within approximately 20 msec of cessation of step a)  
with an adjustable current.

7. A method for providing defibrillation of a human heart from outside of a human body containing the heart, the method comprising defibrillating with an electromotive force of less than or equal to approximately 200 volts.

8. (Amended) A method for providing pacing of a human heart from outside of a human body containing the heart, the method comprising pacing with an [electromotive force of less than or equal to] adjustable current having an amplitude range of between approximately 20 milliamps and approximately 200 [volts] milliamps.

9. A method for providing defibrillation of a heart, the method comprising digitally generating a direct current waveform to the heart.

10. A method for providing pacing of a heart, the method comprising digitally generating a direct current waveform to the heart.

#### REMARKS

The application entitled "Control of Cardiac Muscle" was submitted with ten claims. The following Article 19 amendments were made to the claims in response to receiving the International Search Report:

Claims 2, 4, 5, 7, 9, and 10 remain unchanged.

Claims 1, 3, 6, and 8 have been replaced by amended claims bearing the same numbers.

The amendments were made in response to the documents considered to be relevant and cited in the International Search Report. Substitute sheets showing consecutively numbered claims 1-10 are attached. Favorable action is requested.

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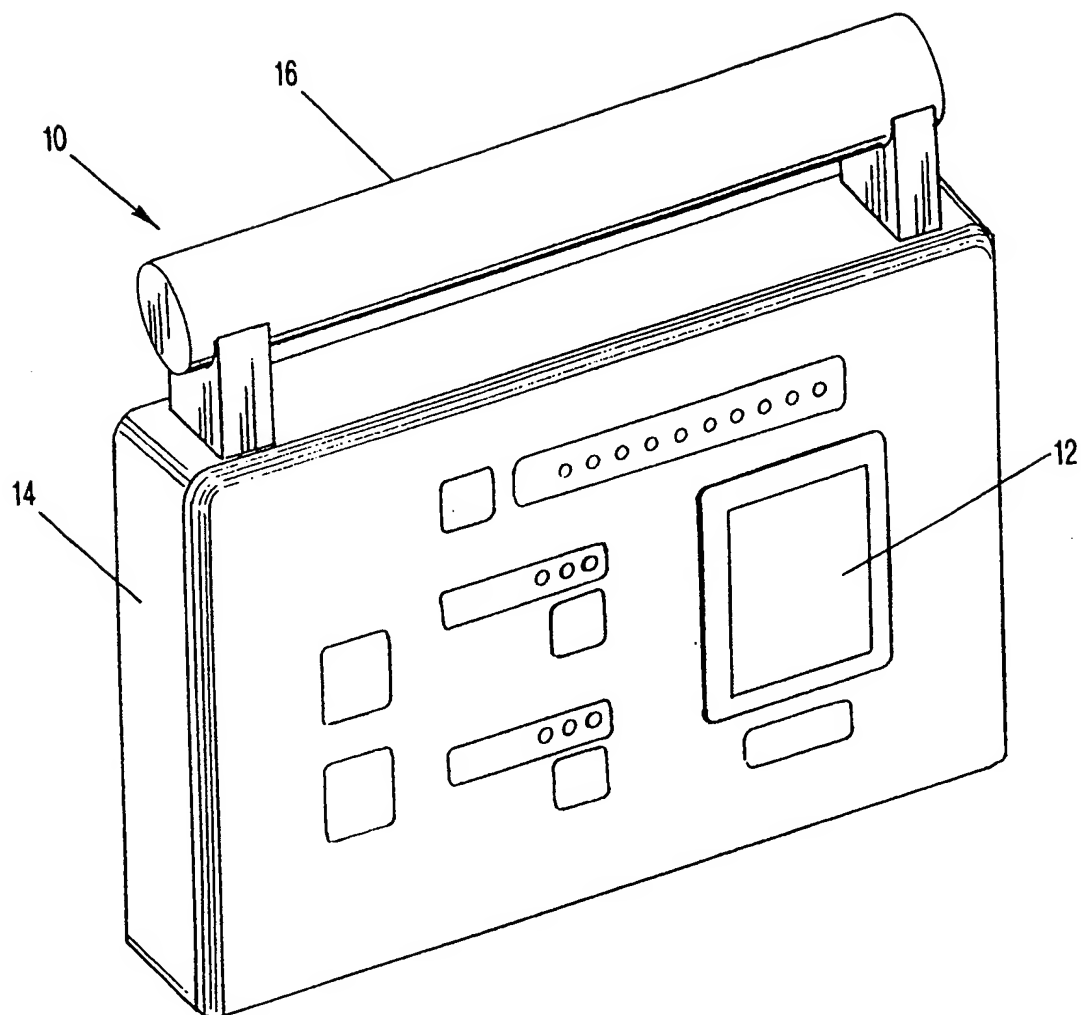


FIG-1

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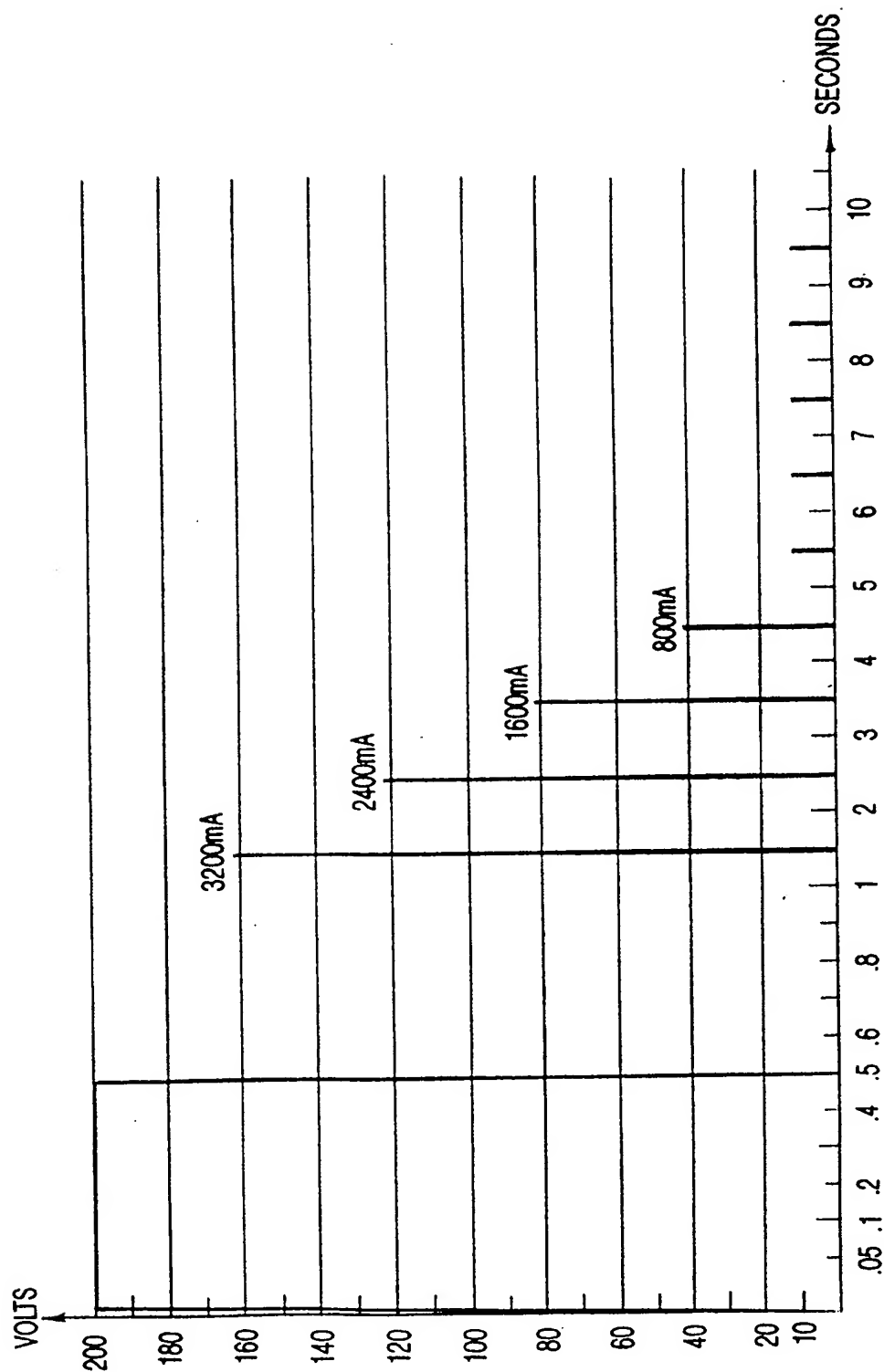


FIG-2



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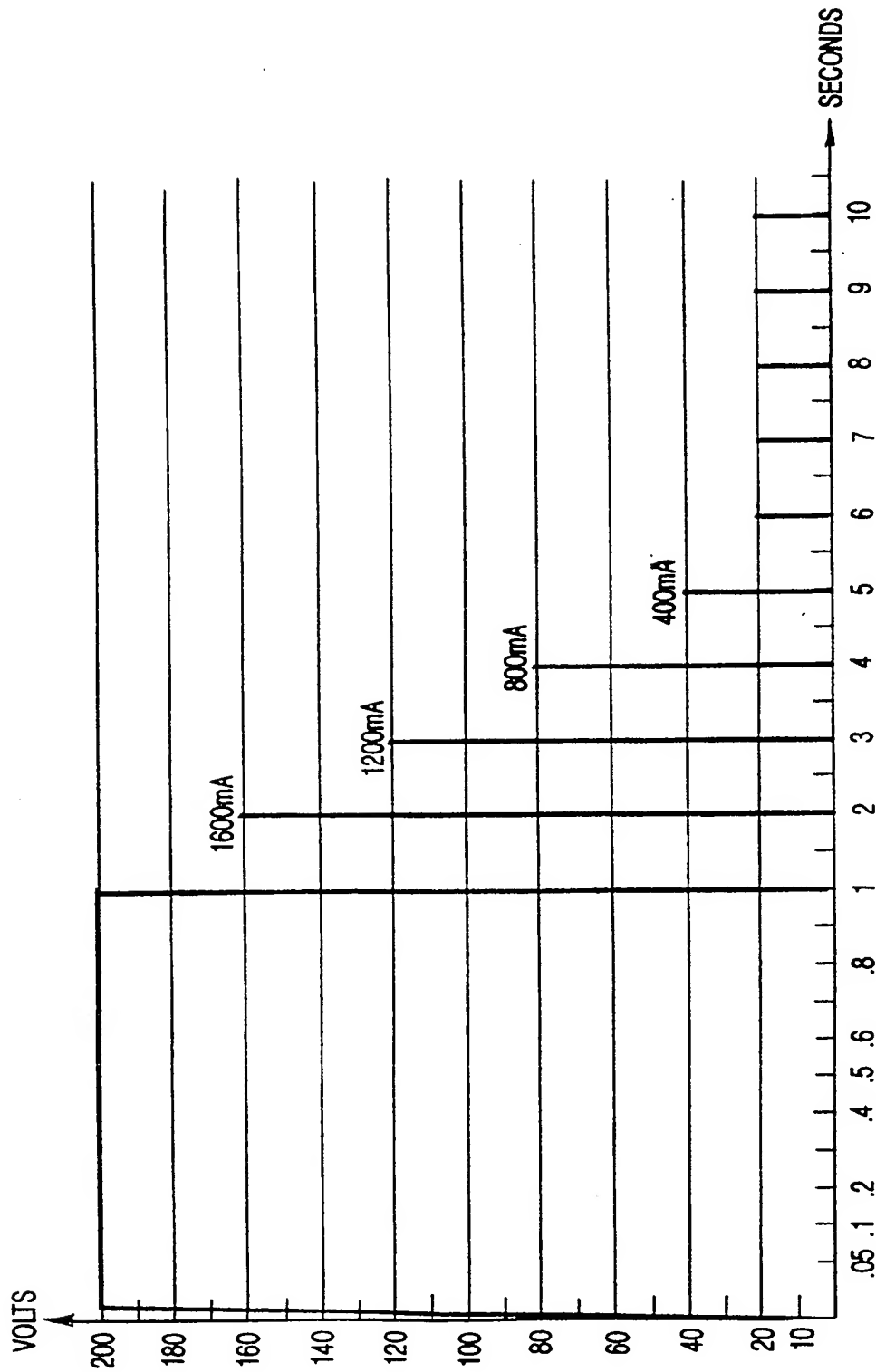


FIG-3

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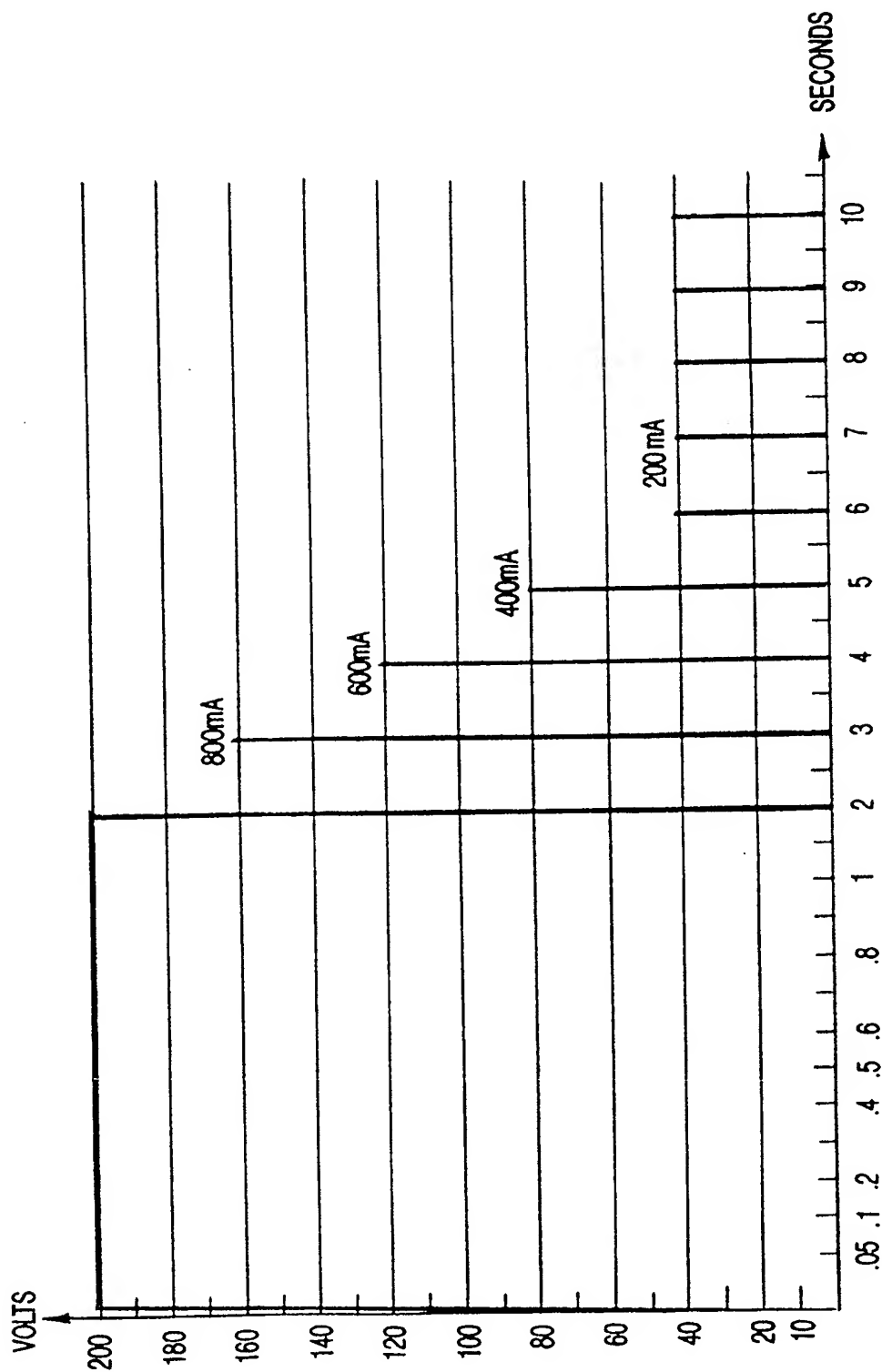
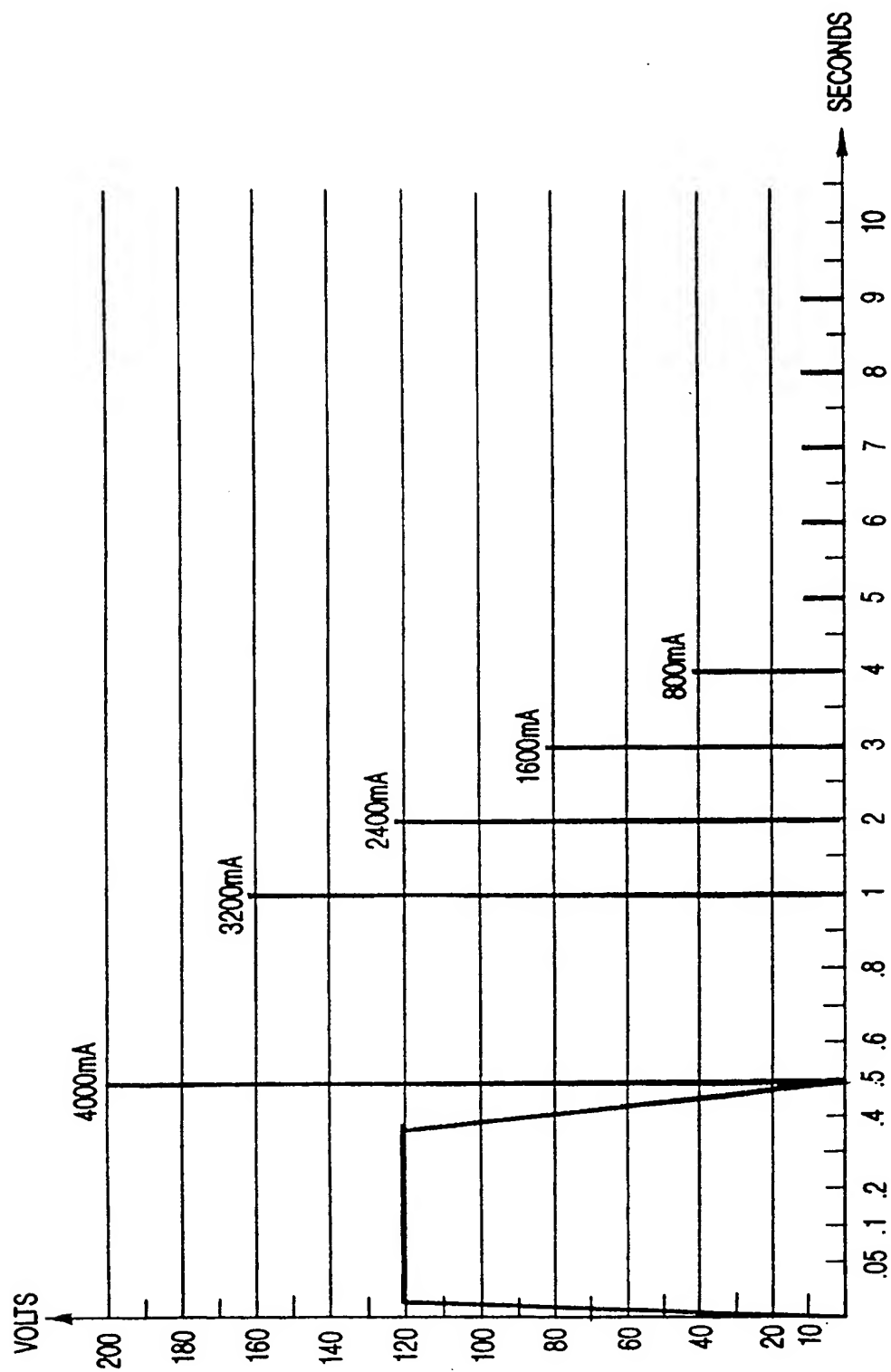


FIG-4

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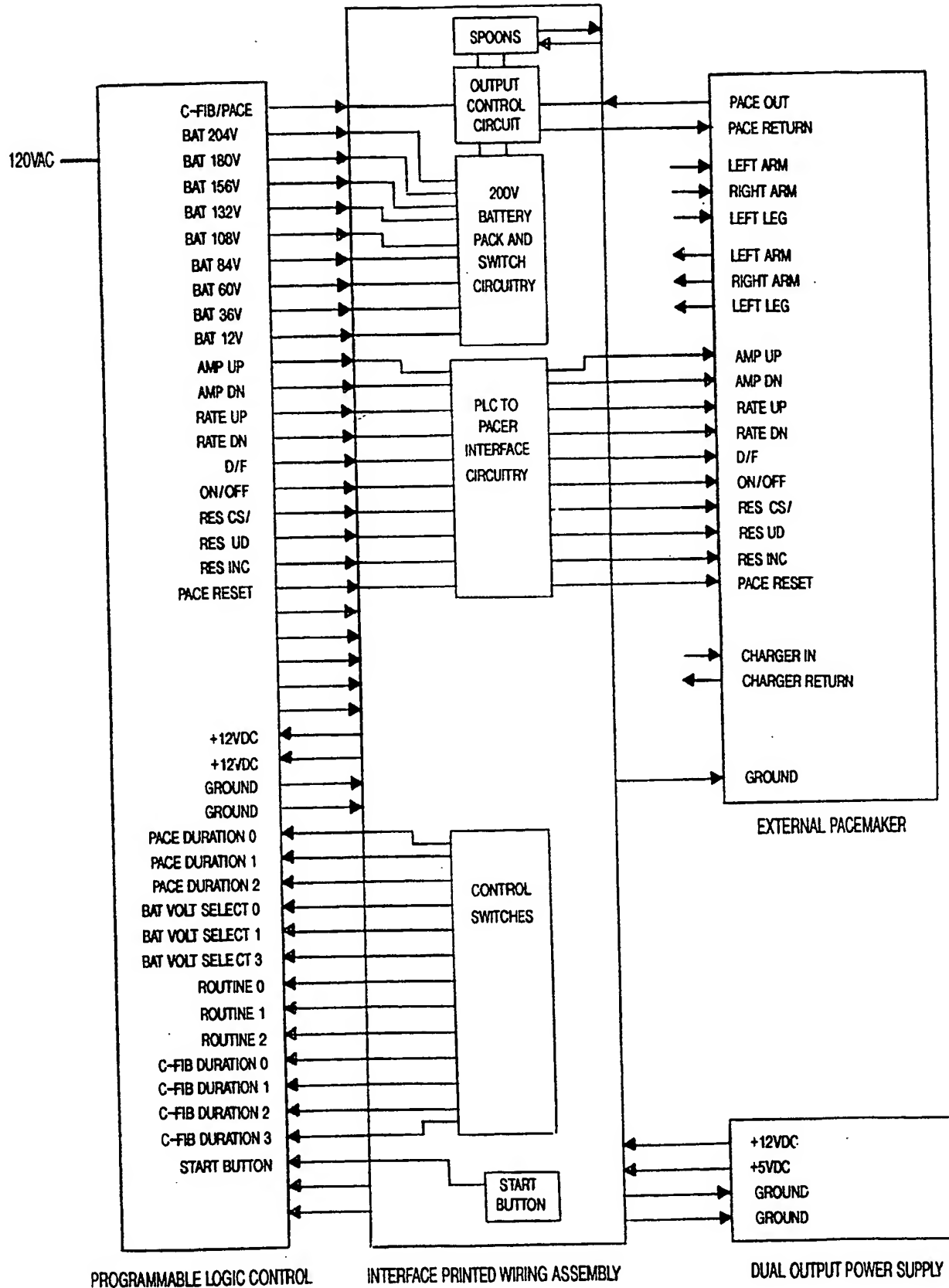


FIG-6

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C-FIB DURATION SWITCH	
SWITCH SETTINGS	DURATION IN SEC.
0	0.5
1	1
2	1.5
3	2
4	2.5
5	3
6	3.5
7	4
8	4.5
9	5
10	NOT USED
11	NOT USED
12	NOT USED
13	NOT USED
14	NOT USED
15	NOT USED

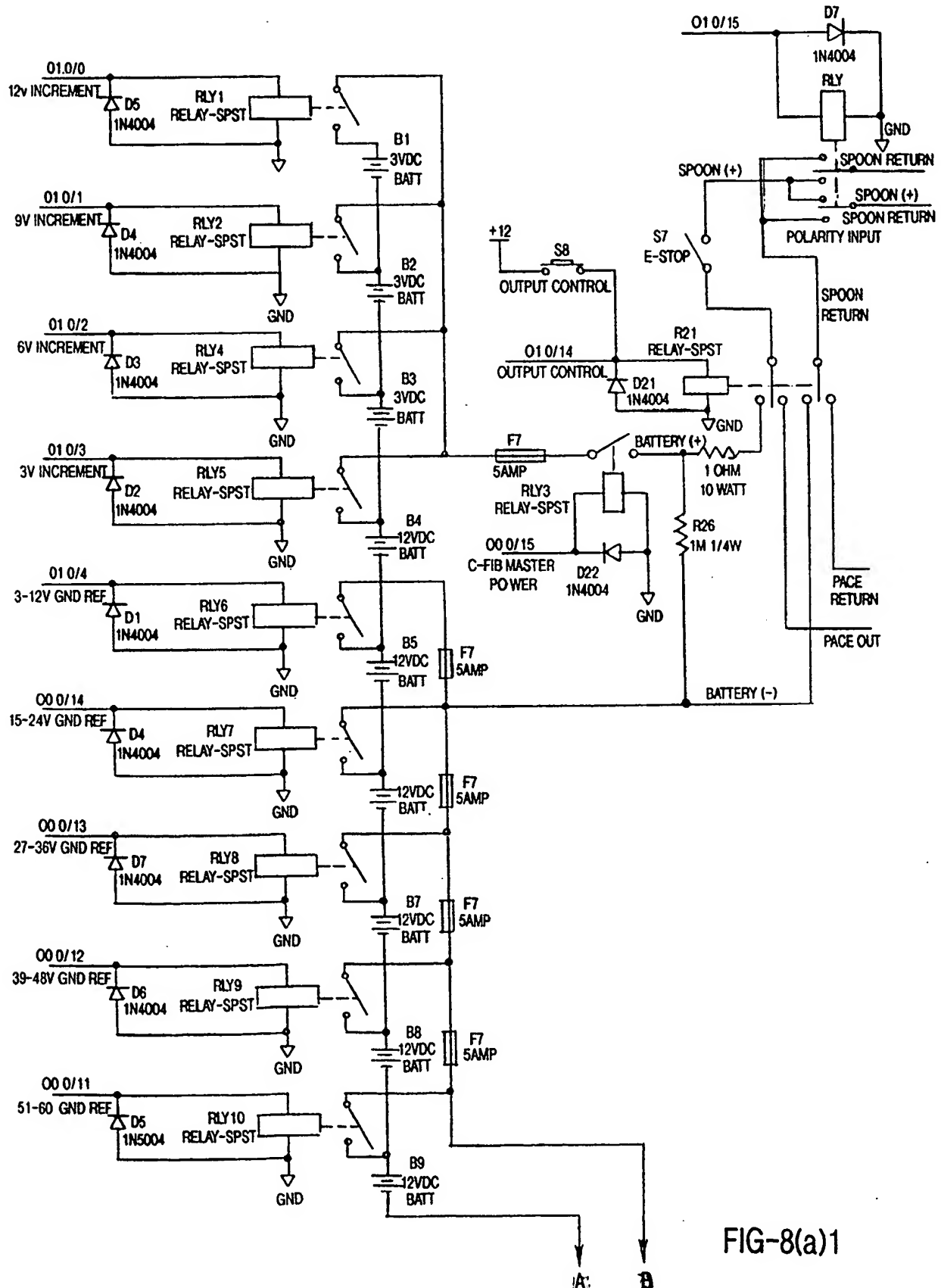
C-FIB AMPLITUDE SWITCH		HIGH VOLTAGE SWITCH		
SWITCH SETTINGS		(ZERO)	(ONE)	(TWO)
0	4	68	132	
1	8	72	136	
2	12	76	140	
3	16	80	144	
4	20	84	148	
5	24	88	152	
6	28	92	156	
7	32	96	160	
8	36	100	164	
9	40	104	168	
10	44	108	172	
11	48	112	176	
12	52	116	180	
13	56	120	184	
14	60	124	188	
15	64	128	192	

PACER DURATION SWITCH		
SWITCH SETTINGS	SELECTION OF K OHMS	PULSE DURATION
0	100	0.1
1	95	0.095
2	90	0.09
3	85	0.085
4	80	0.08
5	75	0.075
6	70	0.07
7	65	0.065
8	60	0.06
9	55	0.055
10	50	0.05
11	45	0.045
12	40	0.04
13	35	0.035
14	30	0.03
15	25	0.025

ROUTINE SWITCH	
SWITCH SETTING	ROUTINE
0	C-FIB PULSE AND 5 TIME CONSTANTS DECREMENT OF PACER AMPLITUDE
1	C-FIB PULSE AND STEADY STATE PACER AMPLITUDE
2	BIPHASIC C-FIB PULSE AND 5 TIME CONSTANTS DECREMENT OF PACER AMPLITUDE
3	BIPHASIC C-FIB PULSE AND STEADY STATE PACER AMPLITUDE
4	STEADY STATE PACING WITH NO C-FIB PULSE
5	C-FIB PULSE WITH NO PACING
6	MULTI-PHASIC C-FIB PULSE AND 5 TIME CONSTANTS DECREMENT OF PACER AMPLITUDE
7	MULTI-PHASIC C-FIB PULSE AND STEADY STATE PACER AMPLITUDE
8	NOT USED
9	NOT USED
10	NOT USED
11	NOT USED
12	NOT USED
13	NOT USED
14	NOT USED
15	BSM MODE

FIG-7

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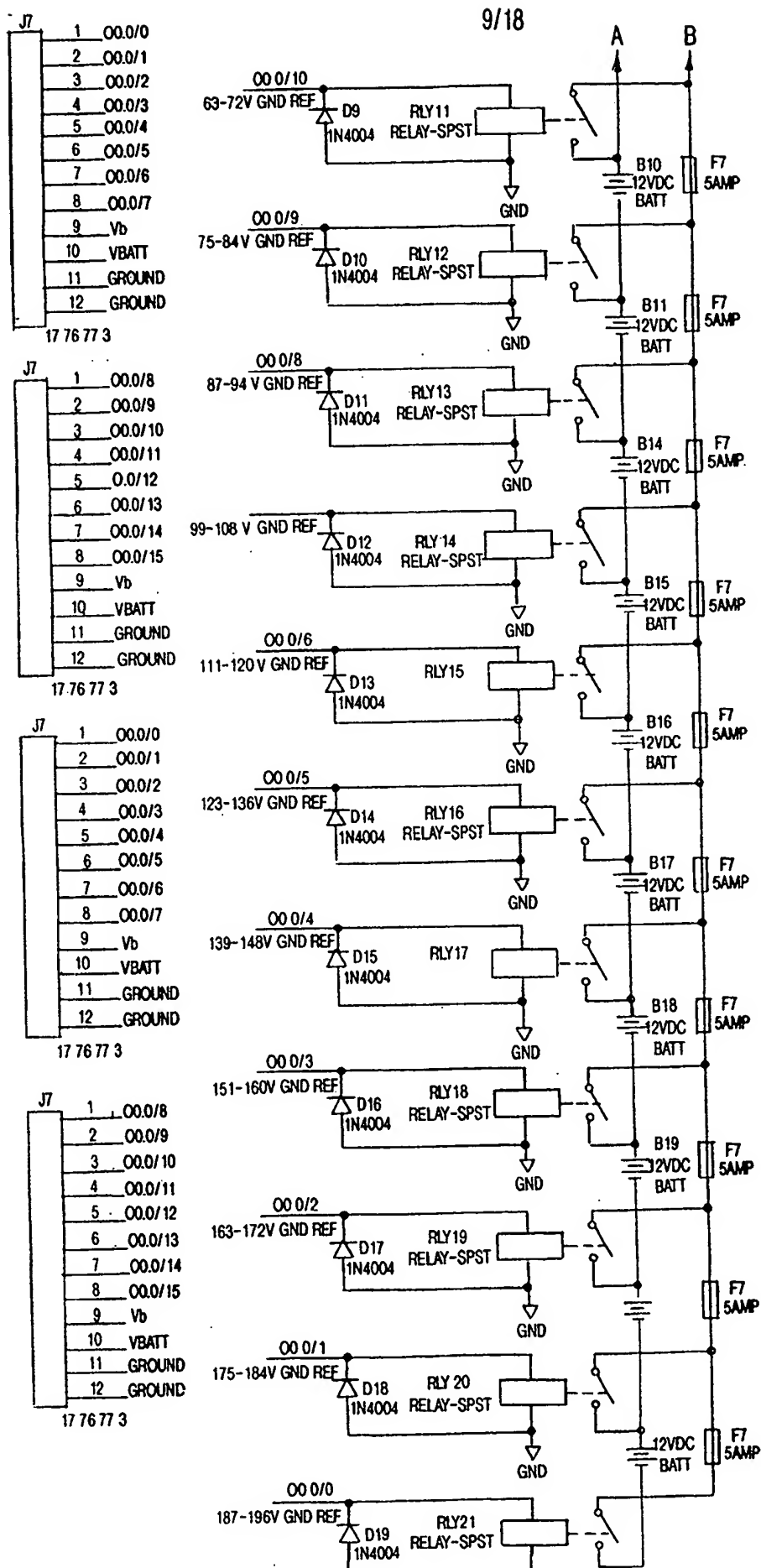


FIG-8(a)2

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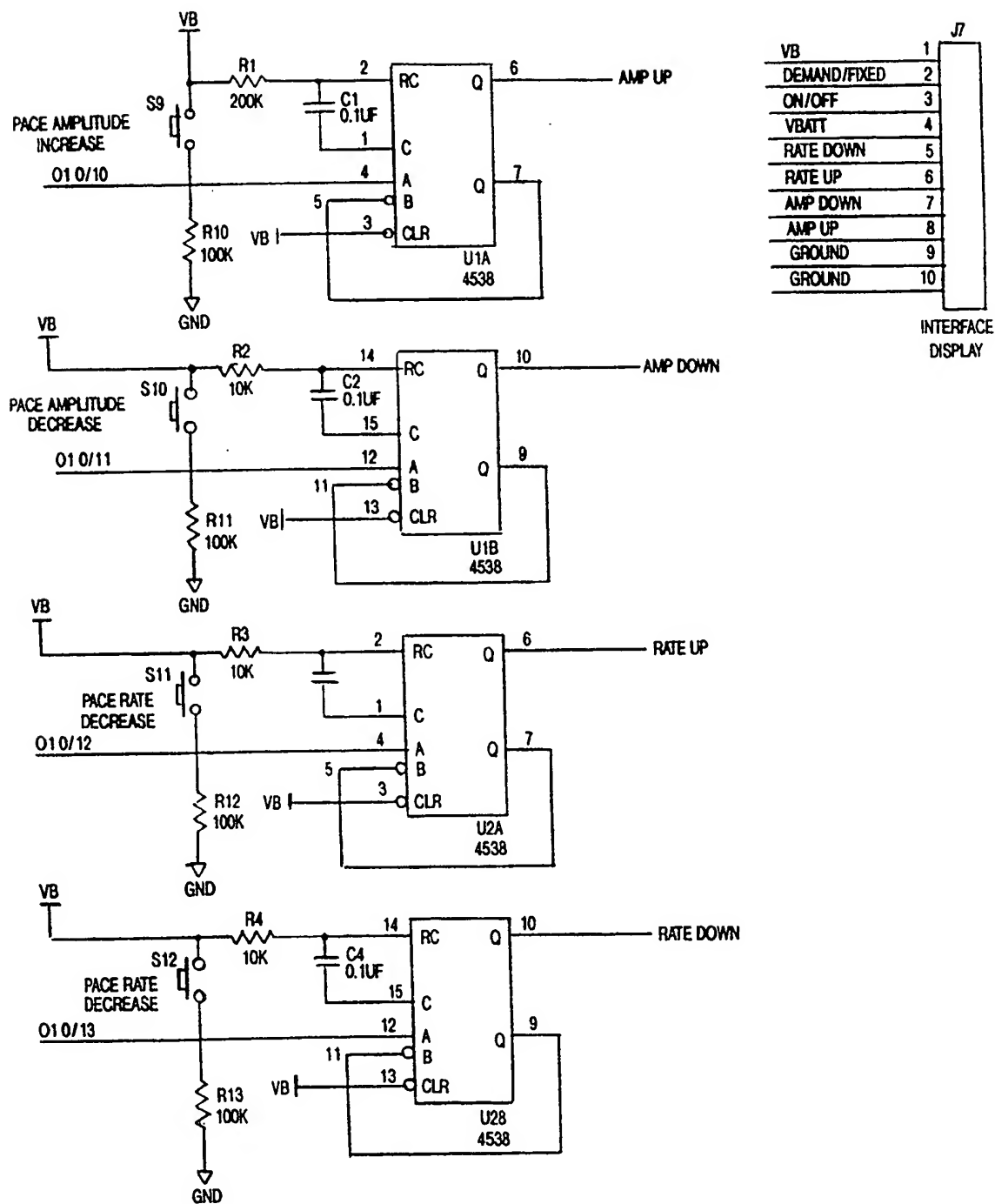


FIG-8(b)1



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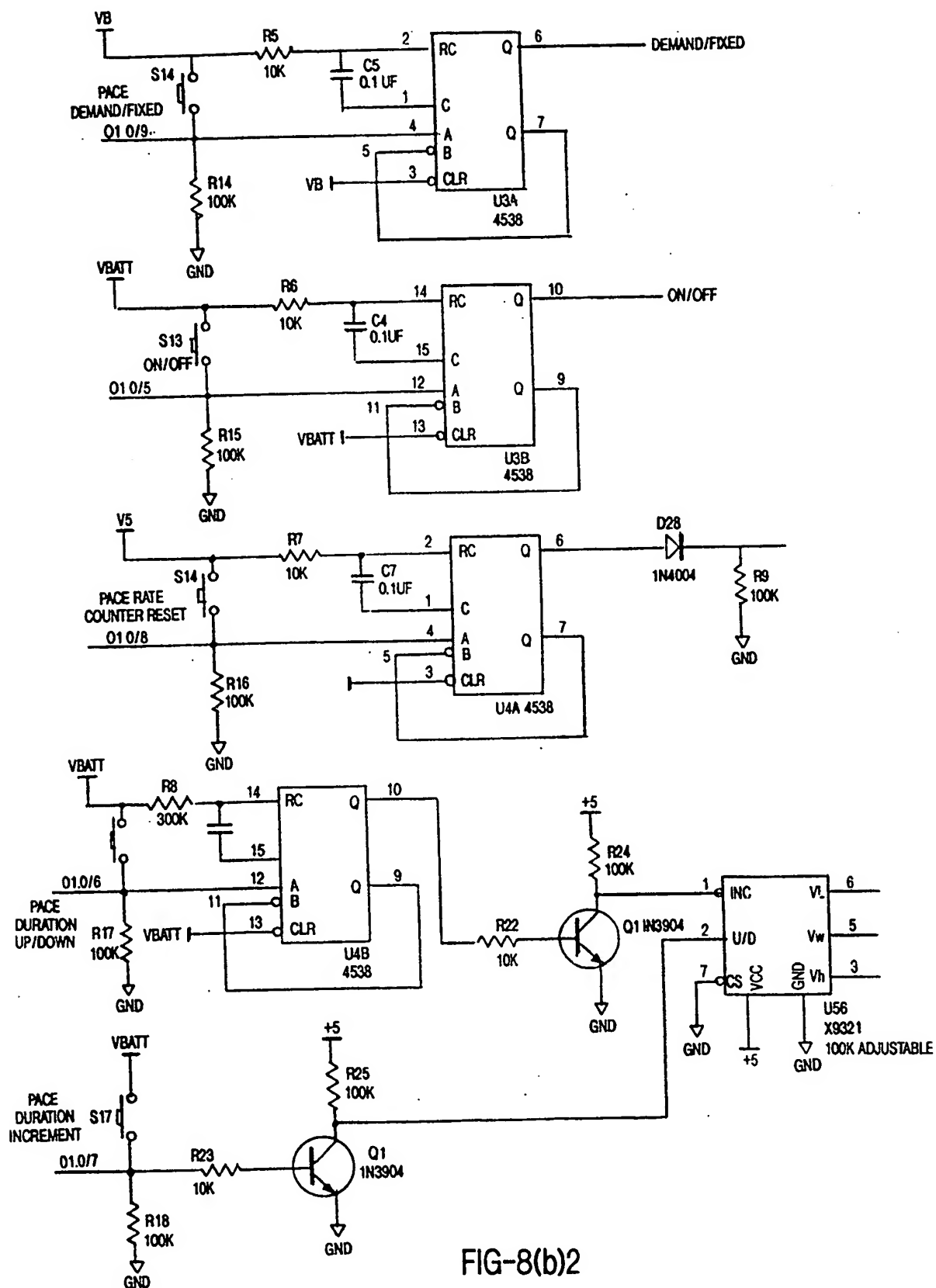
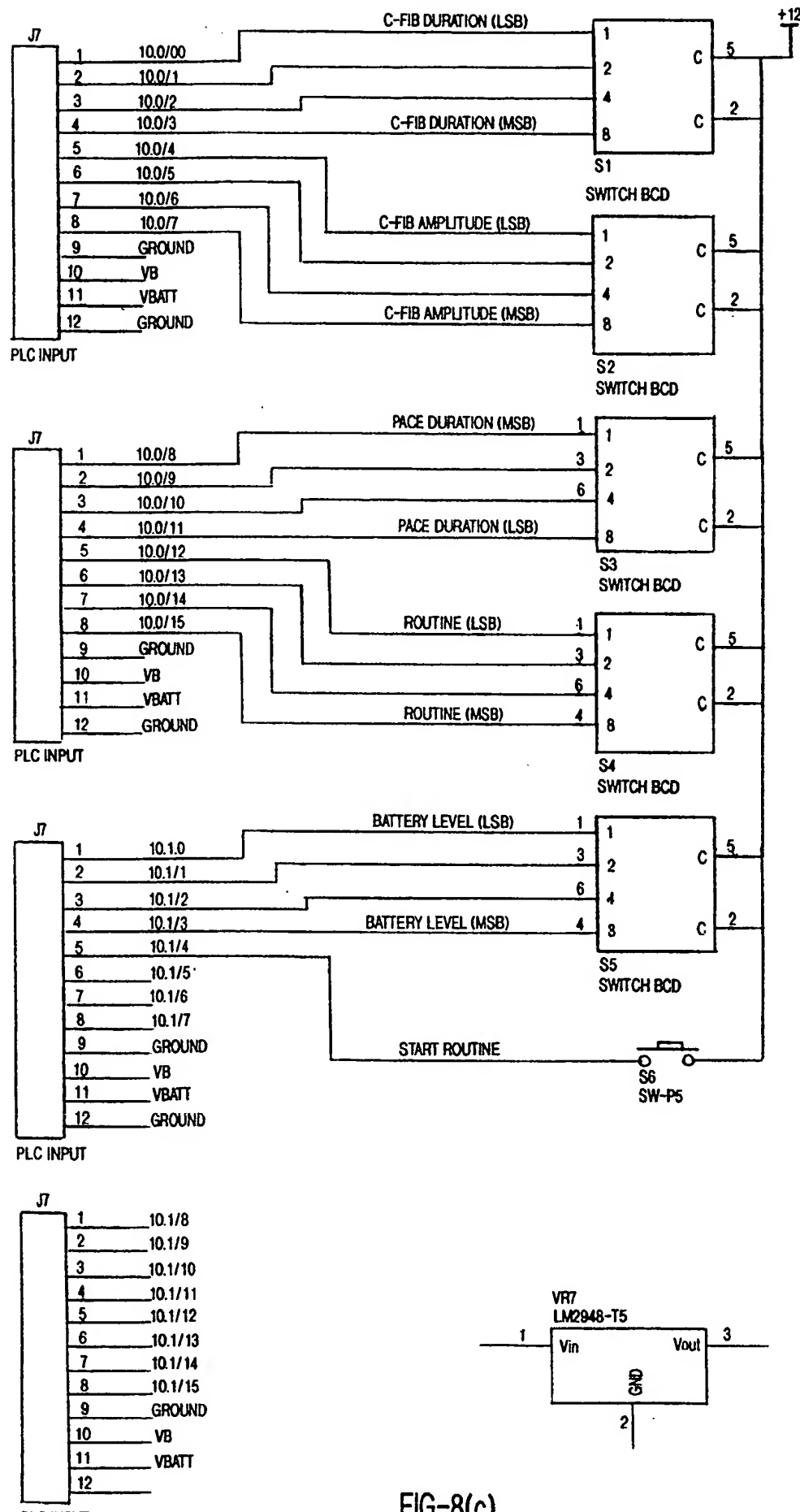


FIG-8(b)2

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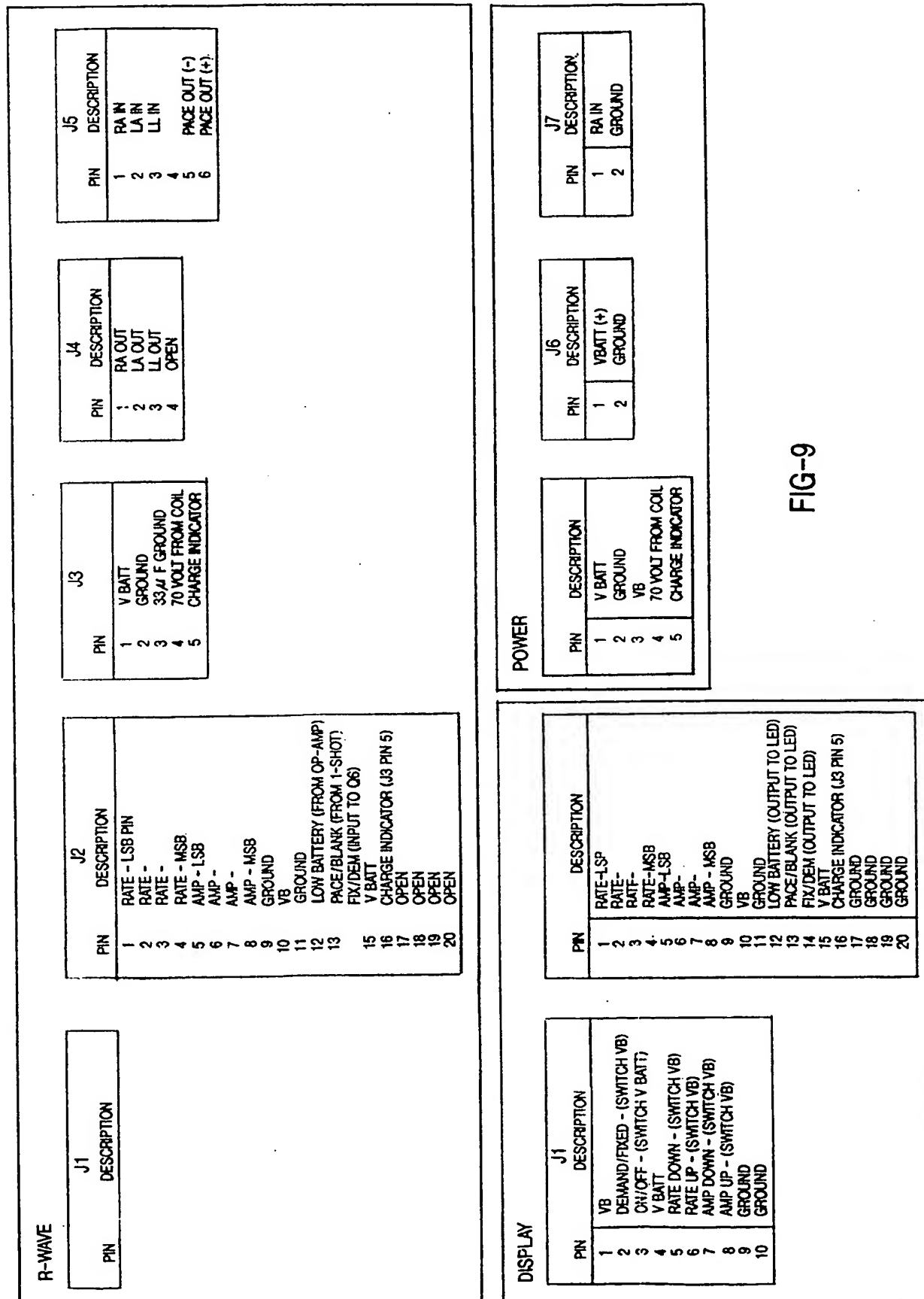


FIG-9

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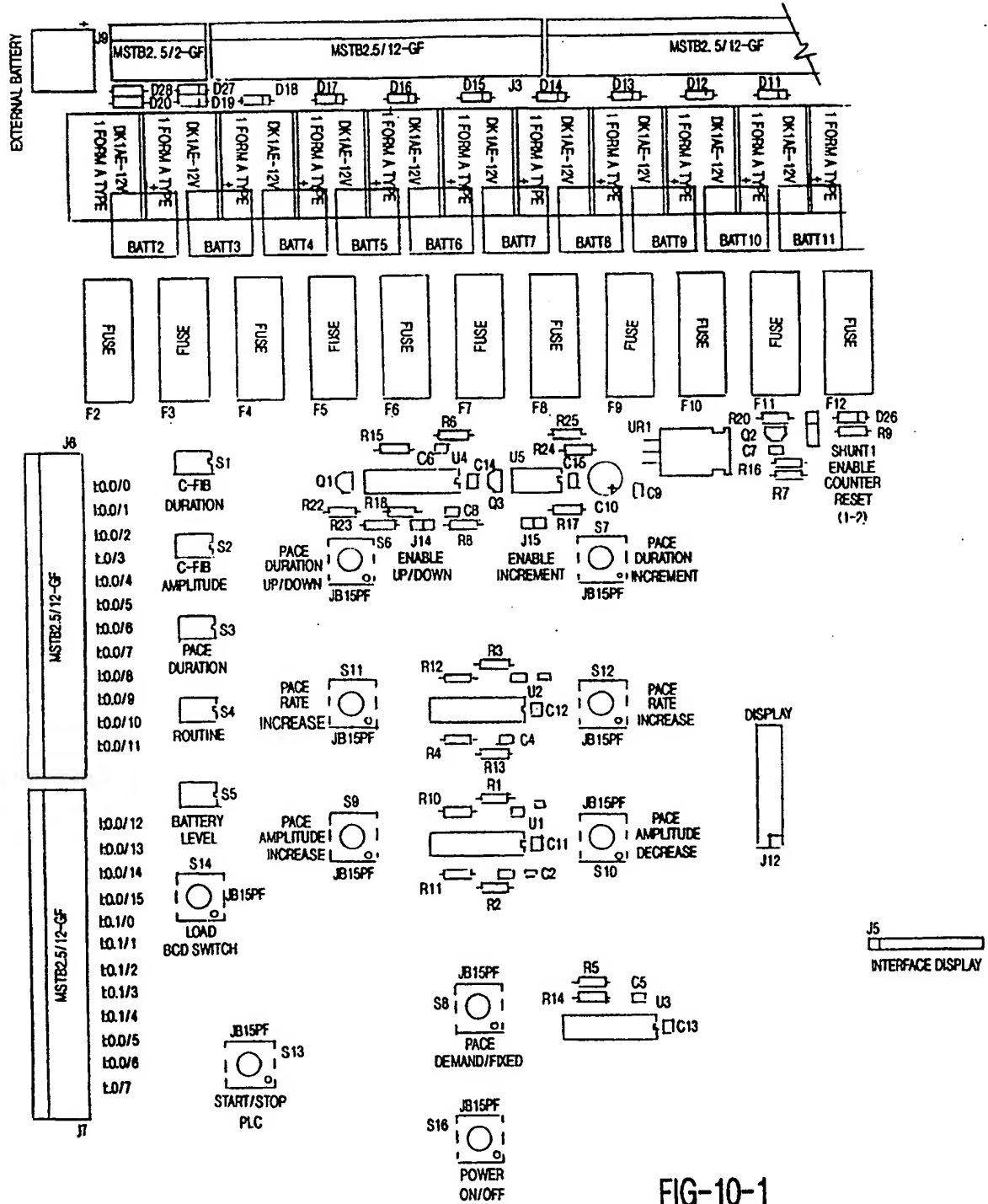


FIG-10-1

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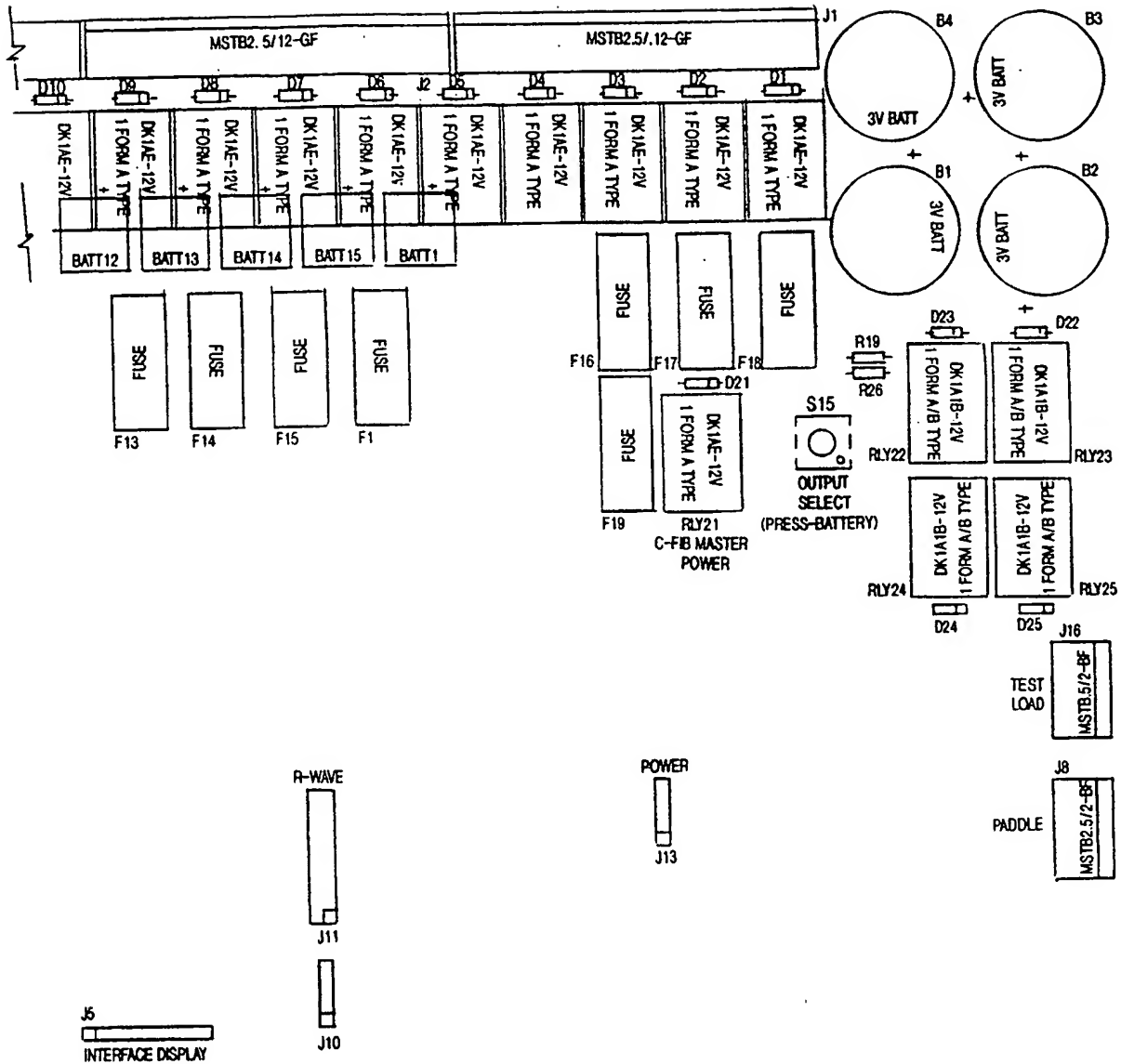
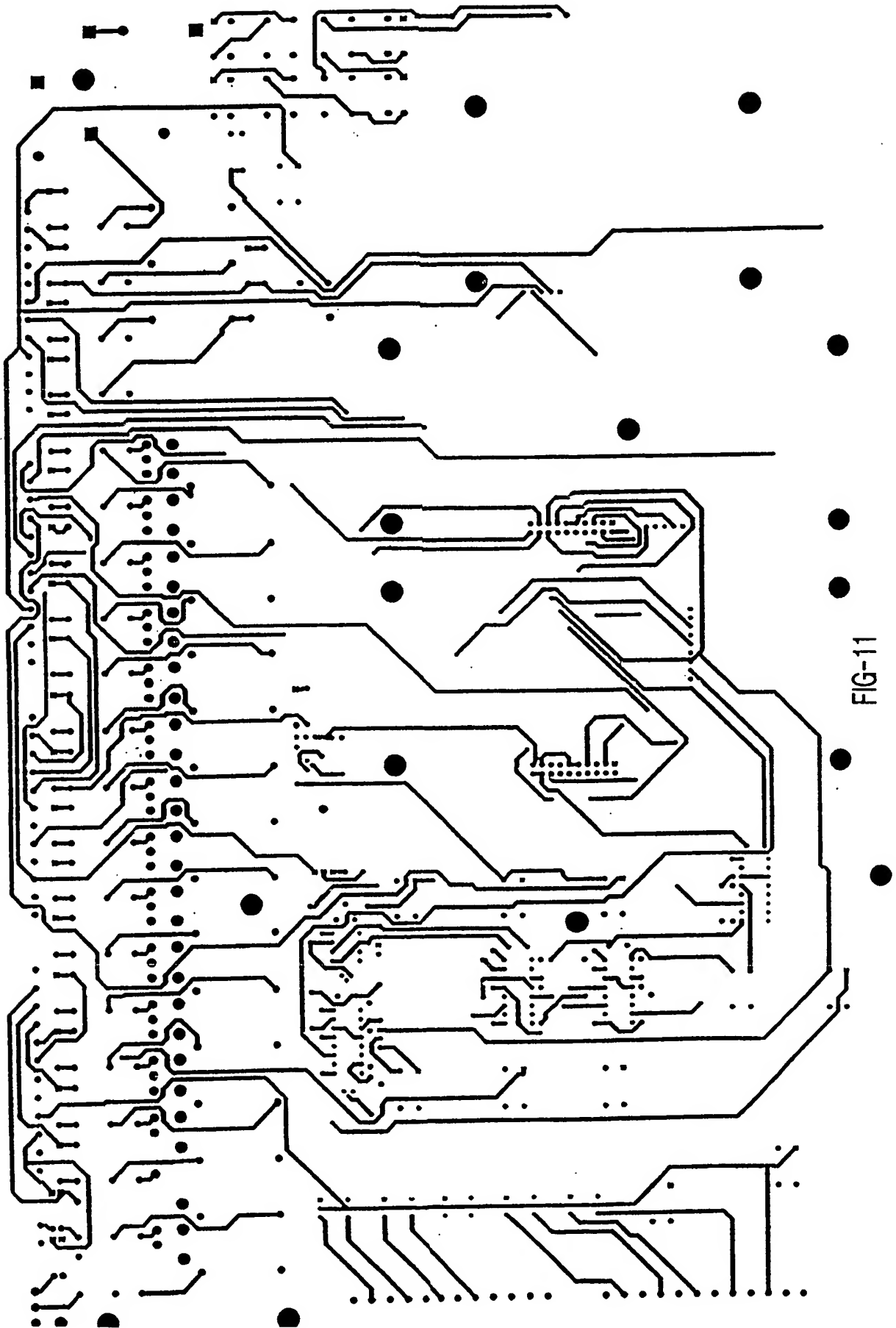
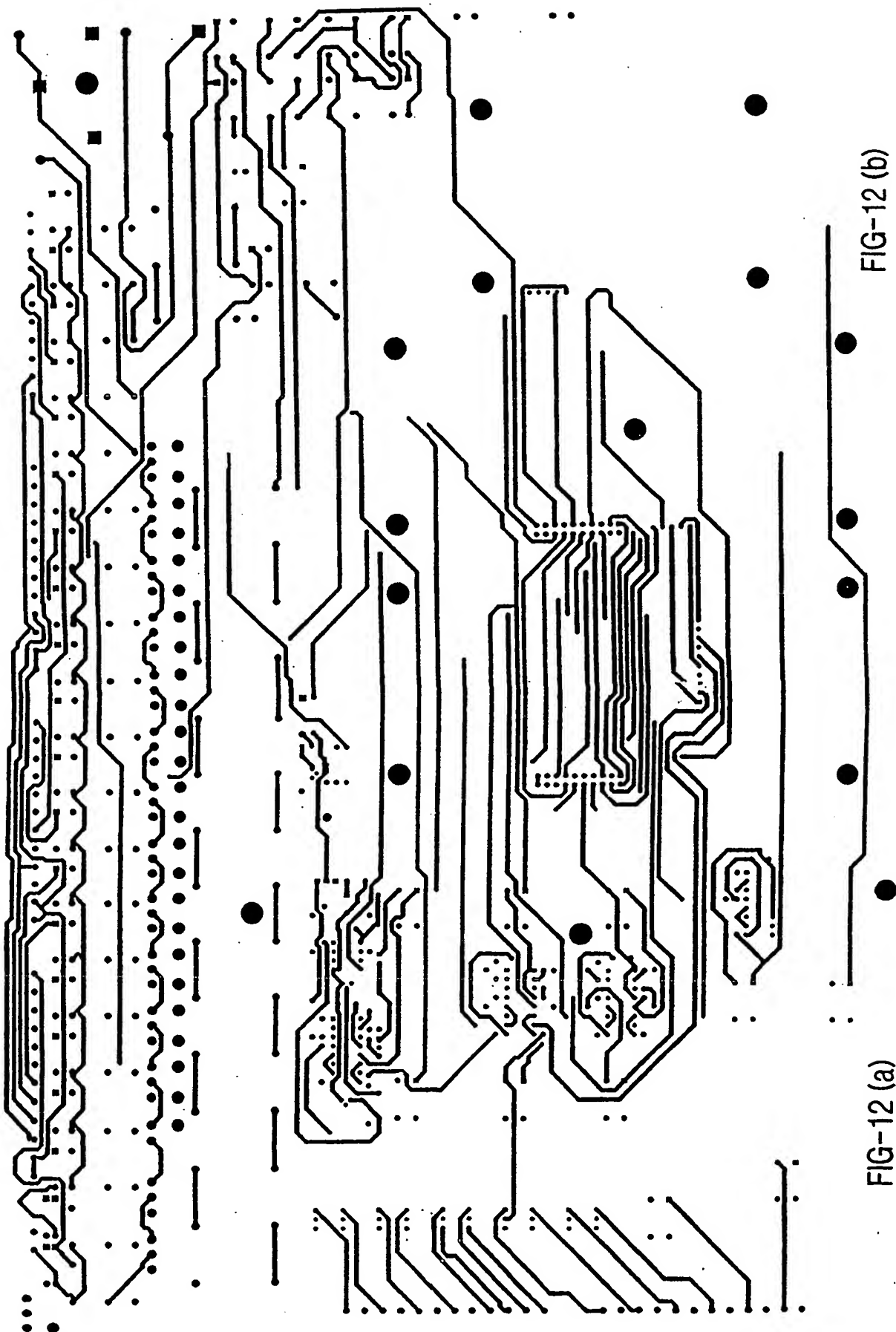


FIG-10-2

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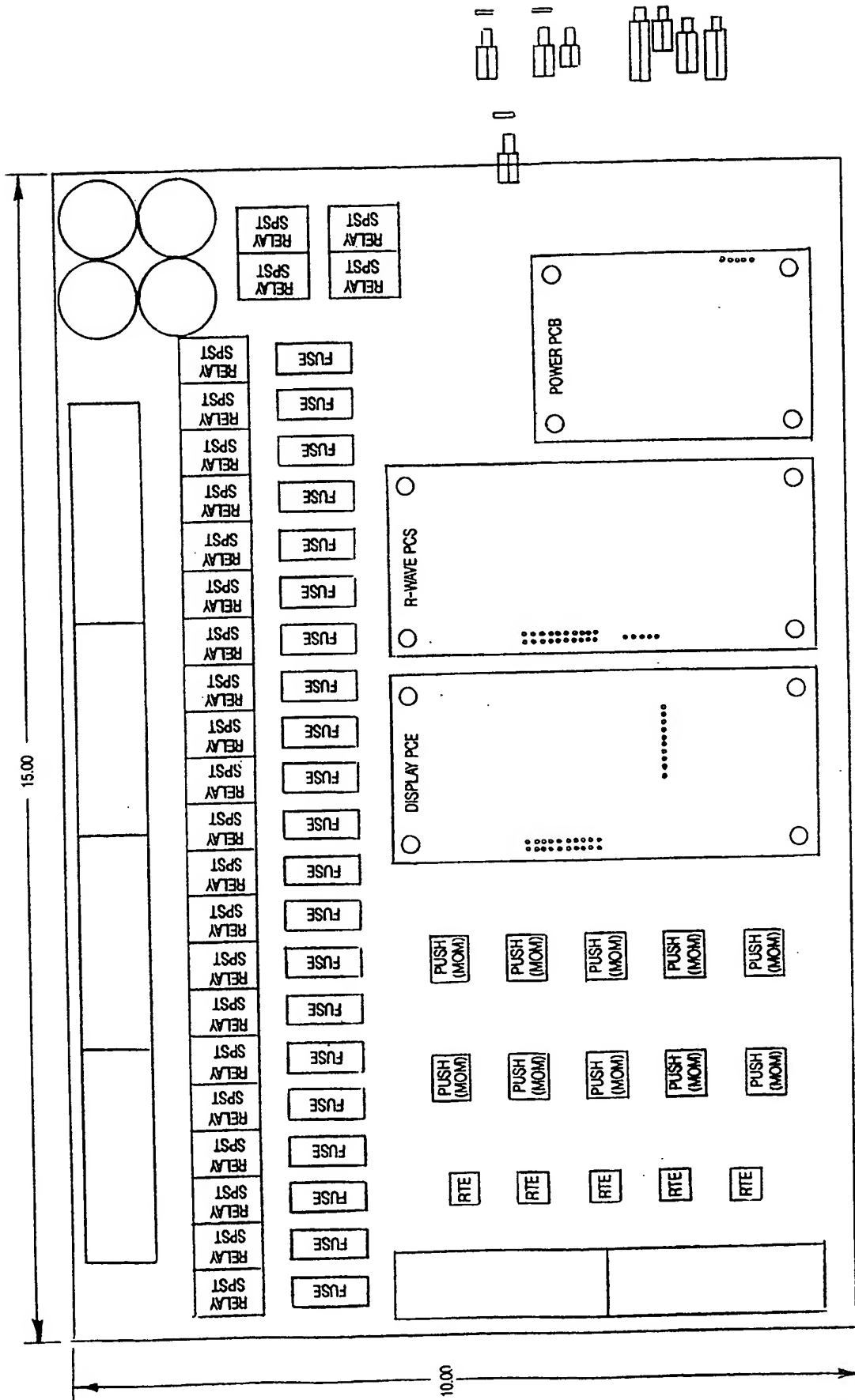


FIG-13 (b)

FIG-13(a)



A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61N1/39 A61N1/362

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 391 187 A (FREEMAN GARY A) 21 February 1995	1,4,5
A	see the whole document ---	2,3
X	CHARBONNIER F M: "EXTERNAL DEFIBRILLATORS AND EMERGENCY EXTERNAL PACEMAKERS" PROCEEDINGS OF THE IEEE, vol. 84, no. 3, 1 March 1996, pages 487-499, XP000590780	1,4,5
A	see the whole document ---	2,3
X	US 5 078 134 A (HEILMAN MARLIN S ET AL) 7 January 1992	1,4,5
A	see the whole document ---	2,3
X	US 4 693 253 A (ADAMS THEODORE) 15 September 1987 see the whole document ---	1-5
	--- -/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

## \* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search

29 September 1998

Date of mailing of the international search report

08. 10. 98

Name and mailing address of the ISA

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Authorized officer

Allen, E

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/14751

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 645 569 A (AYERS GREGORY M) 8 July 1997 see the whole document ---	1,4,5
A	US 5 522 853 A (KROLL MARK W) 4 June 1996 see column 9, line 63 - column 10, line 5 -----	2,3

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 98/14751

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 6-10  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

Information on patent family members

International Application No

PCT/US 98/14751

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			US 5534015 A	09-07-1996